

STATE BOARD OF PHARMACY
STATE OF MISSOURI

MISSOURI BOARD OF PHARMACY,)
)
Petitioner,)
)
v.) Case No. 2008-004397
)
SINKS PHARMACY,)
)
Respondent.)

**FINDINGS OF FACT, CONCLUSIONS OF LAW
AND DISCIPLINARY ORDER**

This matter appears before the Missouri Board of Pharmacy ("Board") pursuant to a Settlement Agreement between Missouri Board of Pharmacy and Sinks Pharmacy, #2005000323. Each Board member participating in this decision read the Settlement Agreement, considered the testimony before the Board, and considered each exhibit admitted into evidence in reaching the decision reflected in this Order.

Findings of Fact

1. The Board set this matter for hearing and served notice of the disciplinary hearing upon Respondent.
2. Pursuant to notice and Section 621.110, RSMo, this Board held a hearing on November 18, 2009, at the Courtyard by Marriott, 3301 LeMone Industrial Boulevard Columbia, Missouri, for the purpose of determining the appropriate disciplinary action against the pharmacy permit of Respondent. Sinks Pharmacy ("Sinks") appeared and with its counsel, Johnny Richardson. The Board was represented by Loretta Schouten. See Transcript page 7.
3. Board members present throughout the disciplinary hearing were James Riddle, Gary Sobocinski, Anita Parran, Barbara Bilek, and Pam Marshall.
4. The Board is an agency of the state of Missouri created and established pursuant to Section 338.110, RSMo, for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.
5. Respondent is licensed by the Board, pharmacy permit no. 2005000323, which permit was current and active throughout the period.
6. The Board and Sinks entered into a Settlement Agreement that is part of the record in which Sinks agreed that there was cause to discipline its permit. See page 13 of the

transcript. The Board incorporates that Settlement Agreement into this Order as if set forth fully herein.

7. In March 2008 a staff pharmacist employed at Sinks Pharmacy during a traffic arrest was found with over a thousand dosage units of controlled substances in his possession. See page 10 of the transcript and Exhibit 1, paragraphs 6-8.

8. In 2008, an audit at Sinks revealed shortages of over 14,000 units of Hydrocodone and over 600 units of Phentermine. See page 10 of the transcript and Exhibit 1, paragraphs 9 and 16.

9. Hydrocodone is a schedule III controlled substance and Phentermine is a schedule IV controlled substance. See Exhibit 1, paragraphs 11 and 12.

10. During the audit identified in paragraph 8 above, the Board's inspector discovered that Sinks' computer software did not correctly identify the dispensing pharmacist on refills. See page 10-11 of the transcript and Exhibit 1, paragraph 16.

11. The owner of Sinks Pharmacy, Sandra Mitchell, testified that the pharmacy did not dispute that the pharmacy violated laws involving the practice of pharmacy. See pages 17-19, 38, and 43 of the transcript.

12. Sandra Mitchell testified that the pharmacy took various actions to make the pharmacy more secure from theft. See pages 21-22, 28-32, and 36 of the transcript.

13. Sandra Mitchell testified that she, as president of Sinks, cooperated with the Board throughout its investigation. See pages 28-29 and 35 of the transcript.

14. Sandra Mitchell testified that Sinks retained a certified public accountant to assist the pharmacy in complying with laws applicable to the practice of pharmacy. See pages 29-31, 50-51 of the transcript. That individual is also registered with the Board as a pharmacy technician. See page 51 of the transcript.

15. Sandra Mitchell testified that Sinks hired a pharmacist compliance monitor, Wilson Winch, to help ensure compliance with the law applicable to licensed pharmacies. See pages 32-34 of the transcript.

16. Mr. Winch provided Sinks with a report dated September 19, 2009. See page 33 of the transcript and Exhibit G.

17. Sandra Mitchell testified that the Board had offered that the pharmacy be placed on five (5) years probation, but she believed the discipline should be limited to a censure. She stated several reasons why the discipline should not include probation, including that it was the pharmacy's first offense, that the pharmacy cooperated with the Board, that the pharmacy acted appropriately and swiftly when it became aware of the problems, the pharmacy also cooperated

with the police investigating the theft of controlled substances, and that it has been proactive in taking steps to avoid problems recurring. See pages 34-37 of the transcript.

18. Sandra Mitchell testified that the owner of a pharmacy is responsible for the security of the pharmacy. See transcript page 43.

19. Sandra Mitchell testified that the loss of 14,000 Hydrocodone tablets was a significant loss. See page 44-45 of the transcript.

20. Sandra Mitchell testified that Exhibit G demonstrated that losses of controlled substances continued at the pharmacy during the time period covered by Exhibit G, but she did not report such losses to the Bureau of Narcotics and Dangerous Drugs or to the Drug Enforcement Administration. See pages 47-50.

21. Amy Mitchell testified that she is a certified public accountant in the state of Missouri and had been since 1993. See page 52 of the transcript.

22. Amy Mitchell testified to various steps she recommended to the pharmacy and that the pharmacy has taken since she started employment with the pharmacy in April 2008. See pages 53-56, 60-61.

23. Amy Mitchell testified that her results of the inventory of controlled substances at Sinks differed from that of Wilson Winch, but she did not assert that Mr. Winch's report was invalid. See pages 61-63. Amy Mitchell testified that she did not believe that there was a loss of controlled substances during the period of her audit. See page 63 of the transcript. Amy Mitchell also testified that the losses of controlled substances during the audit period may have been worse than concluded by Mr. Winch. See page 66 of the transcript.

24. Wilson Winch testified that his audit, Exhibit G, might be in error through his misreading records. See pages 70-71 of the transcript.

25. Mr. Winch testified that the pharmacy has implemented policies and procedures to deter further losses, and that he has never seen a pharmacy that has implemented as many policies and procedures as Sinks has implemented. See pages 73-74 of the transcript.

26. Mr. Winch testified that any loss of controlled substances should be reported. See page 80 of the transcript.

27. Mr. Winch testified that his audit revealed a loss of about 1,000 units of controlled substances. See page 80 of the transcript and Exhibit G.

28. Counsel for Sinks requested that the Board take official notice of disciplinary proceedings that the Board reported in its newsletters of August, May, and February of 2009. See page 83 of the transcript and Exhibit J.

29. Counsel for Sinks stated that he "circled six cases" reported in Exhibit J. See page 83 of the transcript.

30. Counsel for Sinks agreed that the Board should take notice of the actual orders reported in those newsletters. See page 84 of the transcript. The Board incorporates by reference into this Order each of the six cases counsel for Sinks "circled" as if fully set forth herein.

31. Other cases than those circled by counsel for Sinks, in which the Board imposed discipline on pharmacies, also appear in the Board's newsletters. See pages 85-87 and Exhibit J.

32. Counsel for Sinks stated that he believed that imposing a five-year period of probation would be unreasonable, but stated that if the Board did impose a period of probation, it should not exceed two years. See pages 85-86 of the transcript. He also requested that if the Board did place his client, Sinks, on probation, it not be for five years. See pages 90-91 of the transcript.

33. One of the previous cases resolved by the Board that Sinks requested the Board consider in determining the appropriate discipline of Sinks involved Overturf Drug Stores, Inc., permit number 005218. A review of the settlement agreement between the Board and that pharmacy shows that an audit by the Board of that pharmacy revealed a loss of 8,099 tablets. See paragraph 19 of that agreement.

34. One of the previous cases resolved by the Board that Sinks requested the Board consider in determining the appropriate discipline of Sinks involved Wal-Mart Pharmacy #10-0044, permit number 2002009306. A review of the settlement agreement between the Board and that pharmacy shows that an audit by the Board of that pharmacy revealed a loss of 1,047 tablets. See paragraph 22 of that agreement.

35. One of the previous cases resolved by the Board that Sinks requested the Board consider in determining the appropriate discipline of Sinks involved Wal-Mart Pharmacy #10-1188, permit number 2002009518. A review of the settlement agreement between the Board and that pharmacy shows that a targeted audit of that pharmacy revealed a loss of 9,831 tablets. See paragraph 16 of that agreement.

36. One of the previous cases resolved by the Board that Sinks requested the Board consider in determining the appropriate discipline of Sinks involved CVS Pharmacy 8543, permit number 2006015555. A review of the settlement agreement between the Board and that pharmacy shows that pharmacy had a loss of 8,048 tablets. See paragraphs 8 and 9 of that agreement.

37. One of the previous cases resolved by the Board that Sinks requested the Board consider in determining the appropriate discipline of Sinks involved Walgreens Pharmacy, permit number 005543. A review of the settlement agreement between the Board and that pharmacy had a loss of between 285 and 299 tablets. See paragraphs 15 and 16 of that agreement.

38. One of the previous cases resolved by the Board that Sinks requested the Board consider in determining the appropriate discipline of Sinks involved Walgreens Pharmacy #05003, permit number 2000155501. A review of the Consent Order approving the Joint Motion for Consent Order between the Board and that pharmacy shows that pharmacy had a loss of 9 tablets. See paragraph 4 of that Joint Motion.

39. The Board recognizes that it decided each case to which counsel for Sinks referred on its own merits, but also notes that each involved the loss of controlled substances between 9 and 9,831 tablets, while Sinks had a loss of over 14,000 tablets of controlled substances.

Conclusions of Law

40. The Board has jurisdiction over this proceeding in that the parties have agreed that the Board has cause to discipline the permit of Respondent. State Board of Registration for the Healing Arts v. Masters, 512 S.W.2d 150, 160-161 (Mo. App., K.C.D. 1974).

41. The Board has jurisdiction to take disciplinary action against Respondent in that the parties have agreed that such action may be taken.

42. Respondent's license to practice as a pharmacy, numbered 2005000323, is subject to revocation, suspension, probation, or censure by the Board pursuant to the provisions of Section 338.055.2(6), RSMo 2000.

Disciplinary Order

THEREFORE, having considered all of the evidence before this body, and the Settlement Agreement Between Missouri Board of Pharmacy and Sinks Pharmacy, #2005000323, it is the ORDER of the Missouri Board of Pharmacy that the pharmacy permit issued to Sinks Pharmacy, numbered 2005000323, be placed on PROBATION for four (4) years. The following terms and conditions shall govern Sinks Pharmacy's period of PROBATION:

1. Respondent shall pay all required fees for licensing to the Board and shall renew its pharmacy permit prior to October 31 of each licensing year.

2. Respondent shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

3. If requested, Respondent shall provide the Board a list of all licensed pharmacists employed by the Respondent, and the individuals' current home addresses and telephone numbers.

4. If, after disciplinary sanctions have been imposed, the Respondent fails to keep its pharmacy permit current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.

5. Respondent shall report to the Board, on a preprinted form supplied by the Board office, once every six months (due by each January 1 and July 1), beginning with whichever date occurs first after the date of this Order, stating truthfully whether or not it has complied with all terms and conditions of this disciplinary order.

6. Respondent shall not serve as an intern training facility for interns.

7. Respondent shall select an independent pharmacist consultant for the purpose of reviewing and insuring all compliance measures are carried out in accordance with all applicable laws and regulations. The consultant shall be a Missouri-licensed pharmacist whose license is current and not subject to disciplinary action by the Board. Respondent shall submit documentation and credentials of its chosen consultant to the Board office for approval prior to the beginning date of probation. Said consultant shall submit a written plan to the Board office outlining what procedures or changes in operation will be implemented and on what time table is proposed for completion. The consultant shall then provide ongoing reports to the Board office attesting to the pharmacy's compliance or noting deficiencies for each visit made. The visits and initial report shall be provided within thirty (30) days of the beginning of probation. Visits to the pharmacy to assess compliance will be completed at a minimum of a six (6) month cycle and reports to the Board office will be provided once every six (6) months throughout the disciplinary period. The consultant shall be hired at Respondent's expense.

8. Consultant shall perform an audit and reconciliation on all Hydrocodone-containing products and Alprazolam-containing products on each visit to the pharmacy required in section 7. The consultant shall report the results of each reconciliation to the Board office.

9. Respondent shall make a representative of the pharmacy available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said

meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Respondent will be notified and given sufficient time to arrange these meetings.

10. Respondent's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Order.

11. The parties to this Order understand that the Board of Pharmacy will maintain this Order as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

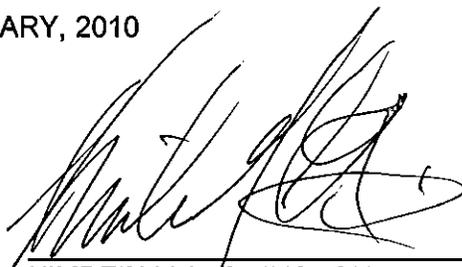
12. Should Respondent violate any term or condition of this disciplinary order or any provision of Chapter 338, RSMo, the Board of Pharmacy may vacate the order of discipline imposed herein and order such further or additional discipline as the Board deems appropriate, including, but not limited to, revocation, suspension, and/or probation against the pharmacy permit of Respondent. No additional order shall be entered by this Board pursuant to this paragraph of this Order without notice and an opportunity for hearing before the Board of Pharmacy as a contested case in accordance with the provisions of Chapter 536, RSMo.

13. Upon the expiration of the period of discipline, Respondent's permit shall be fully restored if all other requirements of law have been satisfied; provided, however, that in the event the Board determines that Respondent has violated any term or condition of this Order, or any provision of Chapter 338, RSMo, the Board, may in its discretion, vacate and set aside the terms and conditions of this Order and order such further or additional discipline as the Board deems appropriate.

14. If the Board determines that Respondent has violated a term or condition of this Order, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Order in its determination of appropriate legal actions concerning that violation.

ENTERED THIS 9th DAY OF FEBRUARY, 2010

(BOARD SEAL)


KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR
MISSOURI BOARD OF PHARMACY

**SETTLEMENT AGREEMENT BETWEEN MISSOURI BOARD OF
PHARMACY
AND SINKS PHARMACY, # 2005000323**

Sinks Pharmacy, #2005000323 (“Licensee”), and the State Board of Pharmacy, (“Board”), enter into this settlement agreement for the purpose of resolving the question of whether Licensee’s license will be subject to discipline.

Pursuant to the terms of § 536.060, RSMo,¹ the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri (“AHC”) regarding cause to discipline Licensee’s license. The parties agree that this matter shall proceed to a disciplinary hearing before the Board consistent with the provisions of §621.110, RSMo.

Licensee acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing at the AHC of the charges against it; the right to appear and be represented by legal counsel; the right to have all charges against it proven upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the AHC hearing against it; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against it; and, subsequently, the right to request the recovery of attorney’s fees incurred in defending this action against its license. Being aware of these rights provided to Licensee by operation of law, Licensee knowingly and voluntarily waives each and every one of these rights and freely enters into this settlement agreement and agrees to abide by the terms of this

¹ All statutory references are to the 2000 Revised Statutes of Missouri, as amended, unless otherwise stated.

document, as they pertain to it. Licensee does not waive, and expressly reserves: its right to a hearing before the Board concerning what, if any, discipline the Board may impose on its license; and, its right to appeal any discipline that the Board may impose on its license.

Licensee acknowledges that it has received a copy of the investigation report and other documents relied upon by the Board in determining there was cause for discipline, along with citations to law and/or regulations the Board believes were violated. The Board will not file a complaint regarding the matters set forth in this agreement, or any other matters currently known to the Board. For the sole purpose of settling, Licensee stipulates that the factual allegations contained in this settlement agreement are true and stipulates with the Board that Licensee's pharmacy license, license no. 2005000323, is subject to disciplinary action by the Board in accordance with the provisions of Chapters 621 and 338, RSMo.

Joint Stipulation of Facts

1. The Board is an agency of the State of Missouri created pursuant to § 338.140, RSMo, for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.
2. Licensee holds a license from the Board as a pharmacy, license no.2005000323 ("license"). Licensee's license was current and active at all times relevant herein, and is presently still active.
3. Licensee is located at 1113 Hauck Drive, Rolla, Missouri, 65401.
4. At all times relevant herein, Licensee had a relationship of professional trust and/or confidence with its customers and the general public.
5. At all times relevant herein, Licensee had a professional duty to maintain adequate security to deter theft of drugs by its personnel and the public.

6. Between June 24, 2002, and March 1, 2008, Shannon Welch (“Welch”) was employed as a staff pharmacist by Licensee.

7. On March 1, 2008, Welch became PIC of another Sinks Pharmacy (“Vienna Store”) located at 606 Highway 63 South, Vienna, Missouri, 65582.

8. On March 23, 2008, Welch was arrested for driving while intoxicated in St. James, Missouri. At the time of the arrest, Welch had approximately 1,000 dosage units comprised of Hydrocodone/APAP, Phentermine, Provigil, Pseudoephedrine, Carisoprodol, and Tramadol.

9. Between November 3, 2006, and April 3, 2008, the following substances could not be accounted for by Licensee:

- a. 206 .25 milligram (mg) tablets of Alprazolam;
- b. 634 0.5 mg tablets of Alprazolam;
- c. 139 5/325 mg tablets of Hydrocodone/APAP;
- d. 2,924 5/500 mg tablets of Hydrocodone/APAP;
- e. 448 7.5/325 mg tablets of Hydrocodone/APAP;
- f. 11,315 7.5/500 mg tablets of Hydrocodone/APAP;
- g. 2,018 7.5/650 mg tablets of Hydrocodone/APAP;
- h. 1,047 10/500 mg tablets of Hydrocodone/APAP;
- i. 121 10/650 mg tablets of Hydrocodone/APAP;
- j. 218 15 mg tablets of Phentermine;
- k. 130 30 mg tablets of Phentermine;
- l. 287 37.5 mg tablets of Phentermine;

- m. 81 100 mg tablets of Provigil;
- n. 2 5 mg tablets of Zolpidem; and
- o. 141 10 mg tablets of Zolpidem.

10. Alprazolam is a schedule IV controlled substance pursuant to § 195.017.8(2)(a), RSMo, and 21 CFR § 1308.14(c)(1).

11. Hydrocodone/APAP in dosages of 5/325, 5/500, 7.5/325, 7.5/500, 7.5/650, 10/325, 10/500, and 10/650 mg is a schedule III controlled substance pursuant to § 195.017.6(4)(d), RSMo, and 21 CFR § 1308.13(e)(1)(iv).

12. Phentermine is a Schedule IV controlled substance pursuant to § 195.017.8(4)(i), RSMo, and 21 CFR § 1308.14(e)(9).

13. Provigil is a schedule IV controlled substance pursuant to § 195.017.8(4)(g), RSMo, and 21 CFR § 1308.14(e)(7).

14. Zolpidem is a schedule IV controlled substance pursuant to § 195.017.8(2)(XX), RSMo, and 21 CFR § 1308.14(c)(50).

15. On March 24, 2008, Welch's employment at the Vienna Store was terminated for theft of controlled substances.

16. Between November 3, 2006, and April 3, 2008, Licensee's electronic data processing ("EDP") system did not correctly identify the dispensing pharmacist on refills.

Joint Conclusions of Law

1. Section 338.055.2, RSMo, provides in pertinent part:

The board may cause a complaint to be filed with the Administrative Hearing Commission as provided by Chapter

621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his certificate or registration or authority, permit or license for any one or any combination of the following causes:

* * *

(6) Violation of ... any lawful rule or regulation adopted pursuant to this chapter[.]

2. 20 CSR 2220-2.010 provides in pertinent part:

* * *

(1)(H) Pharmacies must maintain adequate security in order to deter theft of drugs by personnel or the public. Sufficient alarm systems or locking mechanisms must be in place if the pharmacy is located in a facility into which the public has access and the pharmacy's hours of operation are different from those of the remainder of the facility.

* * *

(1)(O) When a pharmacy permit holder ... should have known, within the usual and customary standards of conduct governing the operation of a pharmacy as defined in Chapter 338, RSMo, that an employee, licensed or unlicensed, has violated the pharmacy laws or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo[.]

3. 20 CSR 2220-2.080 provides in pertinent part:

* * *

(4) Any pharmacy using an EDP system as described in section (1) shall provide documentation that the information concerning the refills of prescriptions entered into the system for all prescription drugs is accurate. This documentation shall include:

(A) The initials or code designation of the dispensing pharmacist for each refill [.]

4. Based on the occurrences described above, Licensee violated 20 CSR 2220-2.010(1)(H) and (1)(O), and 20 CSR 2220-2.080(4)(A) providing cause to discipline its license pursuant to § 338.055.2(6), RSMo.

Additional Provisions

1. The terms of this settlement agreement are contractual, legally enforceable, and binding, not merely recital. Except as otherwise contained herein, neither this settlement agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

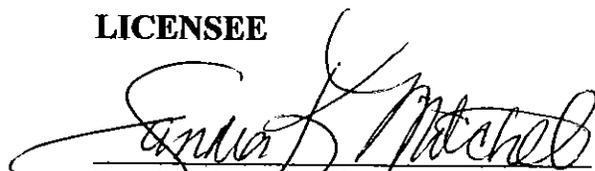
2. Licensee hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former Board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to § 536.087, RSMo, or any claim arising under 42 U.S.C. § 1983, which may be based upon, arise out of, or relate to any of the matters raised in this case, its settlement, or from the negotiation or execution of this settlement agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this settlement agreement in that it survives in perpetuity even in the event that any court of law deems this settlement agreement or any portion thereof void or unenforceable.

3. Licensee understands that it may, either at the time the settlement agreement is signed by all parties, or within fifteen (15) days thereafter, submit the agreement to the Administrative Hearing Commission for determination that the facts agreed to by the parties constitute grounds for disciplining Licensee's license as a pharmacy. If Licensee desires the Administrative Hearing Commission to review this agreement, Licensee may submit its request to: Administrative Hearing Commission, Truman State Office Building, Room 640, 301 W. High Street, P.O. Box 1557, Jefferson City, Missouri 65102.

4. If Licensee requests review, this settlement agreement shall become effective on the date the Administrative Hearing Commission issues its order finding that the settlement agreement sets forth cause for disciplining Licensee's license. If Licensee does not request review by the Administrative Hearing Commission, the settlement agreement goes in to effect fifteen (15) days after the document is signed by the Executive Director of the Board.

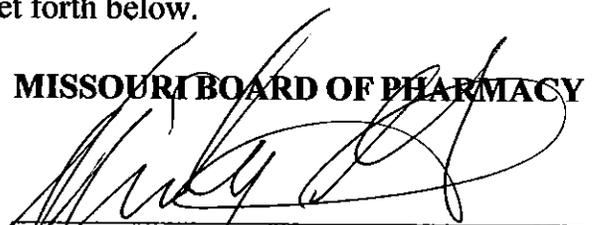
5. Upon this agreement becoming effective, the Board shall set this matter for hearing upon the issue of appropriate disciplinary action and shall notify the licensee of the time and place of the hearing. The Board shall also provide a copy of the notice of disciplinary hearing to counsel for Licensee at the address set forth below.

LICENSEE


By: Sandra Mitchell, President

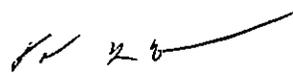
Date: 8/21/09

MISSOURI BOARD OF PHARMACY


Kimberly Grinston
Executive Director
Missouri Board of Pharmacy

Date: 9/28/09

CHRIS KOSTER
Attorney General



DARYL HYLTON
Assistant Attorney General
Missouri Bar No. 35605

P.O. Box 899
Jefferson City, MO 65102
Telephone: 573-751-1444
Facsimile: 573-751-5660
Email: daryl.hylton@ago.mo.gov

**ATTORNEYS FOR MISSOURI
BOARD OF PHARMACY**

**BRYDON, SWEARENGEN &
ENGLAND, P.C.**
Attorneys at Law



JOHNNY K. RICHARDSON
Missouri Bar No. 28744
JAMIE J. COX
Missouri Bar No. 52777
312 East Capitol Avenue
P.O. Box 456
Jefferson City, MO 65102-0456
Telephone: (573) 635-7166
Facsimile: (573) 635-3847
E-Mail: johnnyr@brydonlaw.com

ATTORNEYS FOR THE LICENSEE